

Serial No. 10/791,895  
Response dated August 31, 2009  
In Reply of Office Action dated May 29, 2009

**REMARKS**

The Office Action, dated May 29, 2009, has been received and its contents carefully noted.

In view of the foregoing amendments, and following representations, reconsideration and allowance are respectfully requested.

Examiner Jackson and S.P. Bianco are again thanked for the courtesies extended on design counsel during the interviews of May 7, 2009, and May 11, 2009 and May 12, 2009. The interview summary record filed on May 12, 2009 is incorporated herein by reference.

Applicant points out the following in support of applicant's request for reconsideration and allowance of the allowance of the claims and application.

In sum, applicant has corrected an informality in independent claim 1, and rewritten claim 1 as new independent claim 25 for clarity. Claims 3, 5, 6, and 13 remain withdrawn, and the "claim identifiers" are shown as "withdrawn" in accordance with current practice, even though some of the withdrawn claims have been amended to depend from new independent claim 25.

Serial No. 10/791,895  
Response dated August 31, 2009  
In Reply of Office Action dated May 29, 2009

The application is clearly in condition for Allowance.

As to Examiner Jackson's "Response to Arguments" on page 2 of the Office Action, undersigned counsel respectfully submits that U.S. Design Patent No. D398,989 to Ashlin (hereinafter "Ashlin") would not have been, and could not have been illustrative of "endotracheal tubes that have a flat surface on their insertion end" as argued by the Examiner. That is because Design patents teach only that which is ornamental, and cannot be used to show a utilitarian feature. Further, Ashlin cannot be understood to illustrate "a flat surface", as, assuming for the sake of argument it were usable as a proper reference, there is no basis for such.

First, Ashlin would have failed to teach the "flat surface" on either "end" of Ashlin. That is because Ashlin would have taught only the ornamental appearance for an "endotracheal tube". Second, one cannot note which end in Ashlin is the "insertion and" as asserted by the Examiner, as there is no relevant text in a design patent. Third, Ashlin has no hidden lines, and one cannot determine what the configuration is of either the top or the bottom end in Ashlin, if such is indeed an end. Fourth, there is no section (nor cross section) of either "end" as termed by the Examiner, as Ashlin has no cross section,

Serial No. 10/791,895

Response dated August 31, 2009

In Reply of Office Action dated May 29, 2009

which is typical for design patents. Fifth, Ashlin has no text and one would not have, and indeed, could not have, known which so-called end is intended to be inserted, if any.

As to the objection to the claims because of informalities; i.e. the use of paragraph designations such as "a)", Examiner Jackson is respectfully requested to withdraw the rejection.

Undersigned counsel respectfully submits that this objected to format is used for clarity, ease of readability of the claims, and for ease or reference to particular paragraphs in the claims has been in use for decade, as will be appreciated by a consideration of the tens of thousands of patents which have issued in the past few decades with such paragraph markings.

Further, the paragraph designations of "a)" and then the next paragraph in the same claim being designated paragraph "b)" is acceptable.

Still further, tens of thousands of patents have issued in the past decades in which the paragraphs and the dependent claims have paragraph designations which begin in and refer to the paragraphs in the dependent claim itself. That is current practice and has been done as a standard practice for decades because otherwise Patent Examiners and future readers would assume that paragraphs were lost from the dependent claims in

Serial No. 10/791,895  
Response dated August 31, 2009  
In Reply of Office Action dated May 29, 2009

question, if one were to follow the Examiner's suggestion of "numbering" continuing from a previous claim.

Still further, if such were not done, the "renumbering" or relabeling of each paragraph in each dependent claim whenever the number of paragraphs in earlier dependent claims from which the dependent claim depends changes, or the independent claim itself changes, then each paragraph in each affected dependent would have to be relabeled each time there were such a change. Such would lead to even more claim amendments and even greater burden on inventors, applicants, and Examiners. Such labeling of claim paragraphs is not contradicted by the MPEP nor the rules governing applicant's right to draft claims.

In sum, Examiner Jackson is requested to withdraw the objection to the claims.

First, applicant has added the limitations set forth in new paragraph "f)" of claim 25 and such has never been addressed nor rejected in the past. Thus, no comment is required. The burden is on the Office to reject such newly claimed subject matter.

However, given the unduly long prosecution history of this application, which has been made special, and to expedite the matter, applicant will provide remarks to expedite prosecution.

Serial No. 10/791,895  
Response dated August 31, 2009  
In Reply of Office Action dated May 29, 2009

Thus, to overcome the rejection of the claims as being obvious under 35 U.S.C. 103 over U.S. Patent No. 3,508,554 to Sheridan, modified in view of U.S. Patent No. 5,919,183 to Field, and still further modified in view of the teachings of U.S. Patent No. 7,115,183 to Larson et al., applicant has amended independent claim 1, and rewritten independent claim 1 as new independent claim 25 for clarity.

First, it is respectfully submitted that a person having ordinary skill in the art at the time of applicant's invention would have failed to modify the Sheridan device intended to be inserted in only one direction by the teachings of the Field device, and still further modified in view of the Larson catheter with spiral cut transition member, absent any clear motivation therefor.

Further, assuming for the sake of argument, that such a proposed modification would have been obvious, then applicant's claimed invention still would not have resulted. In sum, Examiner Jackson's proposed modification of those three different Sheridan, Field, and Larson devices, as modified, would have lacked at least applicant's clearly claimed slender dual function flappable insert which has a first insertable end, as well as a second insertable end section, and still further in

integrally attached intermediate section which is deeper than both the first end section and the second end section.

In the Examiner's proposed modification, the resultant device would have had a Sheridan insert in which the material of the catheter was softer as one considers the flexibility of the device as it extended away from the user. This is directly contrary to applicant's invention in which applicant's first and second insertable end sections not only have variable hardness, as defined in independent claim 25, but applicant's claimed intermediate section includes a "stiff, malleable and ductile material stiffer than said soft malleable and ductile first and second insertable end sections."

Still further, a person having ordinary skill in the art would not have made the proposed modification resulting in the proposed structure as argued by the Examiner, as set forth in the following remarks.

The proposed modification of those three (3) different references and devices would not have been obvious as follows.

The Sheridan device can be used in only one way; the depth markings 10 of Sheridan would have taught away from such, and also Sheridan "distal end 6" is clearly shown as terminating at an angle for insertion into a patient, as shown in Sheridan

Serial No. 10/791,895

Response dated August 31, 2009

In Reply of Office Action dated May 29, 2009

Figs. 1 and 2, and the related text. The Examiner's reasoning in the paragraph linking pages 3 and 4 of the Office Action to the contrary, Sheridan "proximal end 8" would not have been insertable into a patient, as the illustrated, flat, non-angled face of end 8 would have gouged and damaged the tissue on insertion.

It would have been readily appreciated by a person having ordinary skill in the art that the Sheridan ends 6 and 8 had completely different configurations, only one of which would logically -- and safely -- be insertable into a patient's throat.

Further, Larson is silent as to any middle Larson section teaching or suggesting applicant's claimed "stiffer than" the Larson outer ends; that is unlike applicant's clearly claimed

g) said intermediate section

positionable in the patient's throat comprising a stiff, malleable and ductile material stiffer than said soft malleable and ductile first and second insertable end sections and having a selected hardness of between about 50 SHORE A to about 90 SHORE D; (Emphasis added).

as set forth in independent claim 25.

Further, Larson would have taught directly away from such:

1. Please see col. 2, lines 49-50 et seq. in which Larson states "The flexibility of the transition member preferably increases along its length." (emphasis added). that is directly contrary to applicant's claimed "intermediate section" being "stiffer than" the claimed "first and second end sections". Even the Larson "outer tube" may have different flexibility than applicant's claimed hardnesses: see col. 3, lines 47-50 et seq. "The outer tube may have [...] distal outer section more flexible than the proximal outer section

Even further, Larson would have taught directly away from such with his: col. 5, lines 21-25 et seq. teaching in which Larson sets forth "As previously stated, the catheter of the present invention includes an outer tube which may have multiple segments including a relatively stiff proximal outer section, a midshaft section of lesser stiffness, and a tapering distal outer section of the least stiffness." (emphasis added). Thus, that Larson outer tube of his catheter decreases in stiffness (has greater flexibility) as it extends away from the one end toward the other; i.e., from the Larson proximal end to the

Serial No. 10/791,895  
Response dated August 31, 2009  
In Reply of Office Action dated May 29, 2009

Larson distal end; that is, the stiffness decreases along its length. Again, that is directly contrary to applicant's claimed "intermediate section" being "stiffer than" the claimed "first and second end sections".

To reiterate, a person having ordinary skill in the art would never have turned around and then inserted the Sheridan device in the wrong direction (i.e., distal end 8 first) into a patient.

Still further, the Examiner's reasoning to the contrary, a "user" would not have used Field's "indicia markings" 10 to mark the depth of the tube in the user [sic patient]; except read them in the opposite direction in order to approximate depth" as such would have been illogical, difficult, and, indeed, risk the safety of the patient.

Contrary to the Examiner's arguments on page 4, the criticality of Applicant's particularly claimed SHORE hardnesses has support in the specification, as filed. Such is not merely a "design choice" as asserted by the Examiner. Please see, for example, page 7, lines 10-25 of applicant's specification, in which applicant set forth SHORE hardnesses and supported the inventive claimed feature that the particular claimed durometer hardnesses relate to:

Serial No. 10/791,895

Response dated August 31, 2009

In Reply of Office Action dated May 29, 2009

The distal section 6 which is softer than the intermediate section 4 passes through the throat and into the esophagus with minimal injury to the tissue. The intermediate section 4 follows the distal section 6 without tissue injury. Once the insert or guide T is positioned, the esophageal airway management device is slid onto the insert or guide T and goes into position in the esophagus with minimal injury. (Emphasis added)

Thus, as set forth above, applicant did establish criticality of the claimed SHORE hardnesses in the application, as filed.

The remaining critical features of applicant's claimed invention that were spelled out in applicant's January 9, 2009 Amendment are incorporated herein by reference.

Thus, Examiner Jackson is requested to consider the above, give weight to each of the particularly claimed features, withdraw the Finality of the rejection, and allow the application.

Applicant has clearly shown the impossibility of modifying the three Sheridan, Field, and Larson references in the manner

Serial No. 10/791,895  
Response dated August 31, 2009  
In Reply of Office Action dated May 29, 2009

argued by the Examiner, has shown the criticality of applicant's claimed features, and that applicant has claimed the configuration, hardness, and use for two (2) different "end sections". Thus, the Examiner may not dismiss applicant's claim limitations by arguing that criticality has not been shown in the specification. Hence, weight must be given to claim features that set forth such:

g) said intermediate section positionable in the patient's throat comprising a stiff, malleable and ductile material stiffer than said soft malleable and ductile first and second insertable end sections and having a selected hardness of between about 50 SHORE A to about 90 SHORE D;

h) said first and second insertable end sections having a SHORE hardness approximately 20% to approximately 30% less than said selected hardness of said intermediate section;

(Emphasis added).

Further, applicant has now claimed in independent claim 25 that each first and second end is "blunt", likewise not

Serial No. 10/791,895  
Response dated August 31, 2009  
In Reply of Office Action dated May 29, 2009

suggested by the Examiner's rejection including the Sheridan, Field, and Larson references:

f) each of said first insertable and second insertable end sections' end tip being a blunt end tip;

In sum, the Examiner is respectfully requested to reconsider his position as regards the newly presented and previously amended claims, withdraw the rejection, and pass the Application on to issue, as applicant has clearly shown that each one of applicant's two markedly physically different claimed "end sections" has different properties and has only one specific claimed configuration and use.

The Application is submitted to be clearly in condition for allowance, with Claims 2-6, 10-13, 22-24, and 25.

Claims 3, 5, 6, and 13 have been previously withdrawn from consideration.

Claims 2,3-6,10-12, and 22, and 23, have been amended.

Claim 25 is in Independent form.

It is believed that no fee is due for this submission. However, should that determination be incorrect, Examiner Brandon Lee Jackson is hereby authorized to charge any

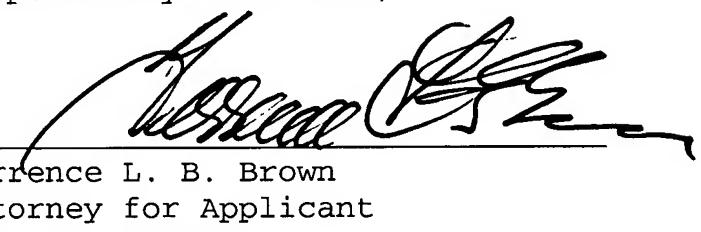
Serial No. 10/791,895  
Response dated August 31, 2009  
In Reply of Office Action dated May 29, 2009

deficiencies to our Deposit Account No. 19-2105 and notify  
undersigned counsel in due course.

Should any outstanding formal matters or other issues  
remain, Examiner Jackson is requested to telephone Terrence  
Brown at 703-684-5600 to resolve such.

Respectfully submitted,

Date: Aug 31, 2009

  
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